## Case4:14-cv-04996-JSW Document1 Filed11/12/14 Page1 of 54

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9	sued as "Johnson & Johnson, Inc."); DEPUY INTERNATIONAL LIMITED (erroneously sued as "DePuy International, Ltd.")						
10		TES DISTRICT COURT					
11	NORTHERN DIS	TRICT OF CALIFORNIA					
12							
13	TATYANA NAKHIMOVSKY,	Case No.					
14	Plaintiff,	NOTICE OF REMOVAL OF					
15	V.	ACTION UNDER 28 U.S.C. SECTION 1441(b) (DIVERSITY)					
16	DEPUY ORTHOPAEDICS, INC.,						
17	JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON, INC.,	JURY TRIAL DEMANDED					
18	DEPUY INTERNATIONAL, LTD., THOMAS P. SCHMALZRIED, M.D.,						
19	9 THOMAS P. SCHMALZRIED, M.D., PROFESSIONAL CORPORATION; and						
20	DOES 1 through 20, inclusive,,						
21	Defendants.						
22							
23	Defendants DePuy Orthopaedics, Inc.	. ("DePuy"), DePuy International Limited, Johnson &					
24	Johnson and Johnson & Johnson Services, In	c. (collectively, "removing defendants"), through					
25	undersigned counsel, hereby remove the state	e-court action entitled <i>Tatyana Nakhimovsky v. DePuy</i>					
26	Orthopaedics, Inc. et al., Civil Action No. Co	GC-14-540916, filed in the Superior Court of					
27	California, County of San Francisco. Remov	ral is warranted under 28 U.S.C. § 1441(b) because					
28	this is a diversity action over which the Cour	t has original jurisdiction under 28 U.S.C. § 1332.					
		1					
	NOTICE OF REMOVAL OF ACTION U	NDER 28 U.S.C. SECTION 1441(b) (DIVERSITY)					

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27 28 In support of removal, removing defendants state as follows:

- On or about August 5, 2014, plaintiff commenced this action against the removing defendants, Thomas P. Schmalzried, M.D., Thomas P. Schmalzried, a Professional Corporation (collectively, "Dr. Schmalzried") and un-named Doe defendants, by filing a complaint in the Superior Court of San Francisco County, in the State of California, bearing case number CGC-14-540916.
- 2. In this action, plaintiff alleges that she suffered various injuries as a result of being implanted with a Pinnacle Acetabular Cup System ("Pinnacle Cup System") marketed and sold by DePuy. (Compl. ¶¶ 25-31.)
- 3. This is one of more than 7,000 similar cases pending around the country involving personal-injury allegations by plaintiffs who were implanted with a Pinnacle Cup System manufactured by DePuy. On May 23, 2011, the Judicial Panel on Multidistrict Litigation issued an order establishing MDL No. 2244, In re: DePuy Orthopaedics Inc., Pinnacle Hip Implant Products Liability Litigation, before Judge Ed Kinkeade in the United States District Court for the Northern District of Texas. Removing defendants intend to seek the transfer of this action to that proceeding, and will shortly provide the MDL Panel notice of this action pursuant to the "tagalong" procedure contained in the MDL Rules.
- 4. As set forth more fully below, this case is properly removed pursuant to 28 U.S.C. § 1441, because the Court has subject-matter jurisdiction over it, pursuant to 28 U.S.C. § 1332, and removing defendants have satisfied the procedural requirements for removal.

## REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT-MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441.

5. The Court has subject-matter jurisdiction over this case pursuant to 28 U.S.C. §§ 1332 and 1441 because this is a civil action in which the amount in controversy exceeds the sum of \$75,000, exclusive of costs and interest, and is between citizens of different States.

#### A. **Complete Diversity Of Citizenship**

6. Plaintiff is a citizen of the State of California. (Compl. ¶ 2.)

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1 7. DePuy is, and was at the time plaintiff commenced this action, a corporation 2 organized under the laws of the State of Indiana with its principal place of business in Warsaw, 3 Indiana, and is therefore a citizen of the State of Indiana for purposes of determining diversity, 28 U.S.C. § 1332(c)(1). 4 5 8. DePuy International Limited is, and was at the time plaintiff commenced this action, a corporation organized under the laws of the United Kingdom with its principal place of 6 7 business in Leeds, England, and is therefore a citizen of the United Kingdom for purposes of 8 determining diversity. 28 U.S.C. § 1332(c)(1). 9 9. Johnson & Johnson and Johnson & Johnson Services, Inc. are, and were at the time 10 plaintiff commenced this action, corporations organized under the laws of the State of New Jersey 11 with their principal places of business in New Brunswick, New Jersey, and are therefore citizens of the State of New Jersey for purposes of determining diversity. 28 U.S.C. § 1332(c)(1). 12 13 10. Dr. Schmalzried and his professional corporation are citizens of the State of 14 California. (Compl. ¶¶ 7-8.) 15 11. Plaintiff also names numerous "Doe" defendants, whose citizenship is disregarded for purposes of removal. 28 U.S.C. § 1441(b)(1). 16 17 12. Thus, plaintiff is diverse from all defendants except Dr. Schmalzried. 18 13. Dr. Schmalzried's presence in the case does not defeat diversity jurisdiction, 19 however, because he was fraudulently joined. Under the fraudulent-joinder doctrine, a court 20 should disregard the citizenship of a defendant where, as here, there is "no possibility that the 21 plaintiff will be able to establish a cause of action in state court against the alleged sham 22 defendant." Taylor v. Jeppesen DataPlan, Inc., No. C 10-1920 SBA, 2010 U.S. Dist. LEXIS 23 106160, at \*5 (N.D. Cal. Sept. 27, 2010) (internal quotation marks and citation omitted); see also McCabe v. Gen. Foods Corp., 811 F.2d 1336, 1339 (9th Cir. 1987). 24

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14. That is precisely the case here. Although plaintiff alleges claims against Dr. Schmalzried for strict liability, negligence, fraud and negligent misrepresentation, there is no possibility that these claims would succeed under California law.

- 15. *First*, there is no possibility that plaintiff would prevail on any of her claims against Dr. Schmalzried because claims like plaintiff's – which rest on either a failure-to-warn theory or a defective-design theory -- are preempted when they are brought against *non-manufacturers* of an FDA-approved product. See PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011); Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013); see also Decl. of Dr. Thomas P. Schmalzried ("Schmalzried Decl.") ¶ 2, Sanchez v. DePuy Orthopaedics, Inc., No. CV 11-7867 (C.D. Cal.) (attached as Ex. 1) (attesting that Dr. Schmalzried "played no role in the manufacturing, packaging, labeling, regulatory submissions, sales, inspection, distribution, and adverse event and complaint reporting, handling or tracking for the Pinnacle Cup System").
- 16. In *Mensing*, the U.S. Supreme Court ruled that all claims against generic drug manufacturers that were premised on a failure to warn are preempted by federal law based on the principle of impossibility preemption. 131 S. Ct. at 2581. According to the Supreme Court, generic manufacturers cannot be found liable on a failure-to-warn theory because generic manufacturers have no power to unilaterally effectuate a label change; rather, they must use the same labels and warnings as those approved by the FDA with respect to the brand-name version of the drug. Id. at 2575-76. Thus, as long as the labels and warnings for the generic form of the drug match the labels and warnings that the FDA has approved for the brand-name form of the drug, generic manufacturers cannot as a matter of law be held liable under state tort law for failing to warn.
- 17. Although Mensing involved failure-to-warn claims, the Supreme Court has reached a similar conclusion as to product-design claims as well. In *Bartlett*, the Supreme Court held that a generic manufacturer could not "legally make [the relevant product] in another composition"

Plaintiff also asserts claims for alleged breach of warranty, but not against Dr. Schmalzried. (See Compl. ¶¶ 60-70.)

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under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Bartlett, 133 S. Ct. at 2475 (internal
quotation marks and citation omitted). As the Court explained, "the FDCA requires a generic drug
to have the same active ingredients, route of administration, dosage form, strength, and labeling as
the brand-name drug on which it is based." <i>Id.</i> (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) and
(8)(B); 21 C.F.R. § 320.1(c)). Because it was "not possible" for the generic manufacturer
defendant in Bartlett to "redesign" the product at issue to make it more useful or less risky, the
Court concluded that causes of action based on a defective design are likewise preempted. See id.;
see also Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 187 (5th Cir. 2012) ("[W]e are
persuaded that [plaintiff's] design defect claim [against generic manufacturer] would be
preempted [under Mensing]."), cert. denied, 134 S. Ct. 57 (2013); Gardley-Starks v. Pfizer, Inc.,
917 F. Supp. 2d 597, 611 (N.D. Miss. 2013) (design-defect claims "are also preempted"); <i>In re</i>
Pamidronate Prods. Liab. Litig., 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) ("the 'federal duty of
sameness,' also applies in the context of generic drug design") (internal quotation marks and
citations omitted).

- 18. As other courts have found, these principles apply in spades to non-manufacturing defendants such as Dr. Schmalzried. After all, these defendants have "no authority" to effectuate changes to the product or its labeling either. *See, e.g., In re Fosamax Prods. Liab. Litig.*, MDL No. 2243 (JAP-LHG), No. 3:08-cv-00008-JAP-LHG, 2012 U.S. Dist. LEXIS 5817, at \*26-28 (D.N.J. Jan. 17, 2012) (because a distributor "ha[d] no authority to initiate a labeling change" and "no power to unilaterally change Fosamax labeling," it "could not independently do under federal law what state law requires of it"); *see also Stevens v. Cmty. Health Care, Inc.*, No. ESCV200702080, 2011 WL 6379298, at \*1 (Mass. Super. Ct. Oct. 5, 2011) ("As a distributor, however, [the defendant] had no ability to change labeling or warnings and thus, like a generic manufacturer, [it] cannot be subject to liability in connection with a state law claim premised on a 'failure to warn.'").
- 19. In *In re Fosamax*, for example, the court granted a distributor's motion for judgment on the pleadings after finding that the plaintiffs' state-law claims were preempted. 2012 U.S. Dist. LEXIS 5817, at \*26-28. The plaintiffs in *Fosamax* asserted a number of claims against

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"the authorized distributor of branded Fosamax" that "emanated from a general theory of failure to
warn," including "defective design, negligence, fraud, misrepresentation, breach of express and
implied warranties, violation of consumer protection statutes, restitution, and loss of consortium."
Id. at *20-21. In rejecting the plaintiffs' claims, the district court ruled that "[a]s a distributor of
Fosamax, [the distributor] ha[d] no power to change Fosamax labeling." <i>Id.</i> at *27. According to
the court, " $[t]$ hat power lies with the applicant who seek $[s]$ approval to market Fosamax" – in
that case, Merck. <i>Id.</i> at *27. Additionally, the court noted that if the FDA had become aware of
new safety information in connection with Fosamax use that it believed should be included in the
labeling, the FDA would have notified Merck – not the distributor. <i>Id.</i> Because the distributor
"ha[d] no authority to initiate a labeling change" and "no power to unilaterally change Fosamax
labeling," it "could not independently do under federal law what state law requires of it." Id. at
*28 (citing <i>Mensing</i> , 131 S. Ct. at 2579) (internal quotation marks omitted). Accordingly, the
court found that "the state law claims brought against [the distributor] [were] preempted." Id.

- 20. Here, all of plaintiff's claims against Dr. Schmalzried rest on either a failure-towarn theory or a defective-design theory. Because Dr. Schmalzried had "no power to unilaterally change" either the design of the FDA-regulated Pinnacle Cup System or the warnings that accompanied it, all of plaintiff's claims against him are preempted.<sup>2</sup> For this reason alone, there is no possibility plaintiff would prevail on any of her claims against Dr. Schmalzried, and he is fraudulently joined.
- 21. Second, even absent preemption, plaintiff's claims against Dr. Schmalzried would have no chance of success under California law.

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Plaintiff's failure-to-test theory is nothing more than a failure-to-warn theory in disguise and is thus barred by Mensing too. See Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 659 (D. Md. 2011) ("Plaintiff contends that her allegation that PLIVA failed to test and inspect its products survives Mensing. The Court fails to see how these allegations are but a piece of Plaintiff's larger failure to warn claims. Accordingly, Mensing preempts these allegations as they relate to Plaintiff's failure to warn claims."), aff'd sub nom. Drager v. PLIVA USA, Inc., 741 F.3d 470 (4th Cir. 2014).

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- 22. Strict Liability. Plaintiff's strict-liability claim against Dr. Schmalzried has no chance of success. Although California allows application of strict-liability theories to participants outside the chain of distribution, the circumstances under which such liability is permitted are extremely narrow. In *Bay Summit Community Ass'n v. Shell Oil Co.*, the court articulated a three-part test for strict-liability claims against a non-manufacturing, non-distributing defendant:
  - (1) the defendant received a direct financial benefit from its activities and from the sale of the product; (2) the defendant's role was integral to the business enterprise such that the defendant's conduct was a necessary factor in bringing the product to the initial consumer market; and (3) the defendant had control over, or a substantial ability to influence, the manufacturing or distribution process.
- 51 Cal. App. 4th 762, 776 (1996). The court went on to explain that the fact that "an entity was a link in the chain of getting goods to the market or that it participat[ed] in marketing a defective product is not enough to establish the defendant should be held strictly liable." *Id.* at 778 (internal quotation marks and citation omitted); *see also Taylor v. Elliott Turbomachinery Co.*, 171 Cal. App. 4th 564, 576 (2009) (a claim for strict liability failure to warn arises only where a plaintiff can prove, *inter alia*, that "the defendant had control over, or a substantial ability to influence, the manufacturing or distribution process"). After all, and as other California courts have held, "[t]here is, implicit in the strict liability standard, a requirement that the defendant have some ability to control the manufacturing or distribution of the product." *Bruce v. Clark Equip. Co.*, No. Civ. S-05-01766 WBS KJM, 2007 U.S. Dist. LEXIS 25331, at \*11 (E.D. Cal. Mar. 26, 2007); *Hanberry v. Hearst Corp.*, 276 Cal. App. 2d 680, 687-88 (1969) (holding that strict liability "should not be extended . . . to a general endorser" that was not "involved in manufacturing products for, or supplying products to, the consuming public").
- 23. Here, plaintiff has not alleged that Dr. Schmalzried controlled, or had any ability to control, the manufacturing or distribution of the product. Nor could he. As set forth in the attached declaration, Dr. Schmalzried "played no role in the manufacturing, packaging, labeling, regulatory submissions, sales, inspection, distribution, and adverse event and complaint reporting,

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handling or tracking for the Pinnacle Cup System." See Schmalzried Decl. ¶ 2. Accordingly, there is no reasonable possibility that plaintiff can prevail on her strict-liability claims against Dr. Schmalzried.

- 24. In addition, plaintiff's design-defect strict-liability claim against Dr. Schmalzried (Compl. ¶ 36(a)) is also barred because, under California law, "the entire category of medical implants available only by resort to the services of a physician are immune from design defect strict liability." Artiglio v. Superior Court, 22 Cal. App. 4th 1388, 1397 (1994); see also Hufft v. Horowitz, 4 Cal. App. 4th 8, 19 (1992) ("As with prescription drugs, the harsher rule of strict liability may discourage manufacturers from researching and marketing new medical devices due to realistic fear of substantial adverse judgments, the high cost of strict liability insurance and the uncertainty that such insurance will even be available. . . . Public interest is served, rather than thwarted, by relieving the manufacturer of strict liability for injuries resulting from implanted medical devices that have been properly fabricated and marketed."). There is no contention anywhere in plaintiff's complaint that her Pinnacle Cup System was obtained other than by the services of a physician.
- 25. Finally, failure to adequately test (Compl. ¶ 36(c)) is not a recognized theory of strict liability under California law. See Kennedy v. S. Cal. Edison Co., 268 F.3d 763, 771 (9th Cir. 2001) ("This doctrine of strict liability extends to products which have design defects, manufacturing defects, or warning defects."); Currier v. Stryker Corp., No. 2:11-CV-1203 JAM-EFB, 2011 U.S. Dist. LEXIS 118408, at \*5 (E.D. Cal. Oct. 13, 2011) (same); Artiglio, 22 Cal. App. 4th at 1392 (same).
- 26. For these reasons too, plaintiff's strict-liability claims against Dr. Schmalzried have zero likelihood of success.
- 27. **Negligence.** Plaintiff's claim for negligence against Dr. Schmalzried is similarly destined to fail because plaintiff cannot establish that Dr. Schmalzried owed any independent duty to her. As set forth in the attached declaration, Dr. Schmalzried was merely one of eight surgeons selected by DePuy to provide advice during the development of the Pinnacle Cup System. See Schmalzried Decl.  $\P$  3. He had no role in the manufacture or sale of the device. *Id.*  $\P$  2. However,

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no duty arises from "being the developer, inventor, or patent holder of a product or design." Murphy v. Aventis Pasteur, Inc., 270 F. Supp. 2d 1368, 1376-77 (N.D. Ga. 2003); see also Weseloh Family Ltd. P'ship v. K.L. Wessel Constr. Co., 125 Cal. App. 4th 152, 164 (2004) (design engineers could not be held liable for general negligence because they owed no duty of care to plaintiff property owners; courts have "invoked the concept of duty to limit [] the otherwise potentially infinite liability which would follow from every negligent act"); In re Rezulin Litig., No. CV 03-1643-R(RZX), 2003 WL 25598915, at \*1 (C.D. Cal. Apr. 28, 2003) (holding that a patent holder and clinical investigator of an allegedly defective prescription drug was fraudulently joined because he "owed no legal duty to any of the plaintiffs, and therefore, there [was] no possibility that the plaintiffs [could] prove a cause of action against [him]").

- 28. These rulings make good sense. Otherwise, every individual who had any role in the design of any component of any product, such as a vehicle, would potentially be liable for negligence any time an individual was injured using it. Such an approach would result in limitless liability for millions of Americans who work in any capacity in which they provide input into the design or manufacturing of any product. Accordingly, our legal system limits liability to the actual manufacturer of a product, which has a duty of care to those who buy its products. See Morrow v. Wyeth, No. B-05-209, 2005 U.S. Dist. LEXIS 43194, at \*13-14 (S.D. Tex. Oct. 13, 2005) (noting that the law places liability on the manufacturer of an allegedly defective product, not on the specific individuals involved in the design and manufacture of the product). For this reason too, Dr. Schmalzried is fraudulently joined.
- 29. Fraud-Based Claims. Plaintiff's claims against Dr. Schmalzried for fraud and negligent misrepresentation (collectively, plaintiff's "fraud-based claims") fail for two reasons: (1) plaintiff does not identify a single statement made by Dr. Schmalzried that was allegedly deceptive; and (2) plaintiff fails to establish any connection between any actions by Dr. Schmalzried and her implantation with the Pinnacle Cup System that could possibly satisfy the reliance/causation elements of her fraud-based claims.
- Causes of action for both intentional and negligent misrepresentation require a plaintiff to prove, inter alia, that the defendant engaged in a misrepresentation and that the

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- 31. Importantly, the "mere assertion of reliance is insufficient" to support fraud-based claims; rather, a "plaintiff must allege the specifics of his or her reliance on the representation to show a bona fide claim of actual reliance." Cadlo v. Owens-Illinois, Inc., 125 Cal. App. 4th 513, 520 (2004). This is particularly true because the elements of plaintiff's fraud-based claims must be alleged with the specificity required under Federal Rule of Civil Procedure 9(b). See, e.g., Baltazar v. Apple, Inc., No. CV-10-3231-JF, 2011 WL 588209, at \*3 (N.D. Cal. Feb. 10, 2011) (holding that plaintiff must satisfy the pleading requirements of Rule 9(b) in order to state a claim for negligent misrepresentation); In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig., 826 F. Supp. 2d 1180, 1204 (C.D. Cal. 2011) (granting motion to dismiss UCL claims where plaintiffs failed to meet the heightened pleading requirements of Rule 9(b)); BBG Props., Inc. v. Eaton, 342 F. App'x 919, 920 (5th Cir. 2009) (affirming trial court's refusal to remand case to state court where the plaintiff "had not stated its fraud claim with sufficient particularity" as required by Rule 9(b)).
- 32. Here, plaintiff has not identified any specific statements that Dr. Schmalzried allegedly made to her (or her doctors) regarding the safety or efficacy of the Pinnacle Cup System. Nor has she alleged that she (or her doctors) relied on any such statements in selecting the Pinnacle Cup System. For both of these reasons, there is no "possibility" that plaintiff can recover

against Dr. Schmalzried on her negligent-misrepresentation and fraud claims. See, e.g., Aronis v. Merck & Co., No. CIV. S-05-0486 WBS DAD, 2005 WL 5518485, at \*1 (E.D. Cal. May 3, 2005) (finding fraudulent joinder of a distributor where "plaintiff d[id] not allege that [the distributor] contributed in any way to her injuries"; "[t]o state a claim against a defendant, a plaintiff must allege a causal connection between the injury and the conduct of that defendant"); BBG Props., 342 F. App'x at 920 (affirming trial court's refusal to remand case to state court where the plaintiff "had not stated its fraud claim with sufficient particularity" with regard to the non-diverse defendant as required under Rule 9(b)); Druker v. Fortis Health, No. 5:06-cv-00052, 2007 U.S. Dist. LEXIS 402, at \*11-13 (S.D. Tex. Jan. 4, 2007) (finding fraudulent joinder where the plaintiff "failed to lodge any meaningful factual allegations" and did not allege specific material misrepresentations upon which he relied as required by Rule 9(b)).

33. For all of these reasons, there is no possibility plaintiff would prevail on any of her claims against Dr. Schmalzried; accordingly, Dr. Schmalzried is fraudulently joined.

## B. Amount In Controversy

- 34. Plaintiff claims that she has suffered "severe pain" (Compl. ¶ 26) and "severe and possibly permanent injuries, pain, suffering and emotional distress" (*id.* ¶ 31). Plaintiff seeks actual damages, including "[p]ast and future lost wages, medical and incidental expenses" and punitive damages. (*See id.*, Prayer For Relief.)
- 35. It is widely recognized that personal-injury claims facially meet the \$75,000 jurisdictional threshold. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 296 (S.D.N.Y. 2001) (finding that a complaint alleging various injuries from taking a prescription drug "obviously asserts a claim exceeding \$75,000"). In addition, compensatory and punitive damages in excess of the jurisdictional amount of \$75,000 have been awarded in product-liability cases in California. *See, e.g., Stewart v. Union Carbide Corp.*, 190 Cal. App. 4th 23 (2010); *Karlsson v. Ford Motor Co.*, 140 Cal. App. 4th 1202 (2006); *Jones v. John Crane, Inc.*, 132 Cal. App. 4th 990 (2005).
- 36. Other federal courts have similarly concluded that the amount in controversy exceeded \$75,000 in pharmaceutical cases. *See, e.g., Smith v. Wyeth, Inc.*, 488 F. Supp. 2d 625,

630-31 (W.D. Ky. 2007) (denying motion to remand); *Copley v. Wyeth, Inc.*, No. 09-722, 2009 WL 1089663 (E.D. Pa. Apr. 22, 2009) (same).

37. Given plaintiff's claim that she has suffered "severe and possibly permanent injuries, pain, suffering and emotional distress" and her request for punitive damages, it is evident that the amount of recovery sought by plaintiff exceeds \$75,000.

# II. REMOVING DEFENDANTS HAVE SATISFIED THE PROCEDURAL REQUIREMENTS FOR REMOVAL.

- 38. DePuy, Johnson & Johnson & Johnson & Johnson Services, Inc. were each served with plaintiff's Complaint on October 13, 2014. DePuy International Limited was served on October 16, 2014. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b).
- 39. The Superior Court of San Francisco County is located within the Northern District of California. *See* 28 U.S.C. § 84.
- 40. None of the removing defendants is a citizen of the State of California, the State where this action was brought. *See* 28 U.S.C. § 1441(b).
- 41. It is well settled that co-defendants who are fraudulently joined need not join in the removal. *See Borsuk v. Mass. Mut. Life Ins. Co.*, No C 03-630 VRW, 2003 U.S. Dist. LEXIS 25259, at \*7-8 (N.D. Cal. Sept. 4, 2003). As set forth above, Dr. Schmalzried is fraudulently joined. *See* Section I.A, above. Therefore, he need not consent to removal.
  - 42. No previous application has been made for the relief requested herein.
- 43. Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings and orders served upon removing defendants, which papers include the complaint, are attached collectively as Exhibit 2.
- 44. Pursuant to 28 U.S.C. § 1446(d), a copy of this Notice of Removal is being served upon counsel for plaintiff and a copy is being filed with the Clerk of the Superior Court of the County of San Francisco.

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WHEREFORE, removing defendants respectfully remove this action from the Superior 1 2 Court of the County of San Francisco, in the State of California, bearing Number CGC-14-3 540916, to this Court. Respectfully submitted, 4 5 Dated: November 12, 2014 **BARNES & THORNBURG LLP** 6 7 Alexander G. Calfo 8 Kelley S. Olah Gabrielle Anderson-Thompson Attorneys for Defendants 9 DEPUÝ ORTHOPAEDICS, INC.; 10 JOHNSON & JOHNSON SERVICES, INC.; JOHNSON & JOHNSON 11 (erroneously sued as "Johnson & Johnson, Inc."); DEPUY INTERNATIONAL 12 LIMITED (erroneously sued as "DePuy International, Ltd.") 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

# EXHIBIT 1

1	Ralph A. Campillo (Bar No. 70376)				
2	Wendy A. Tucker (Bar No. 121122)				
	Michael M. Walsh (Bar No. 150865)				
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8	michael.walsh@sedgwicklaw.com Attorneys for Defendant	n			
9	THOMAS P. SCHMALZRIED, M.D.				
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11	TINITED STATES	DISTRICT COURT			
		IFORNIA, WESTERN DIVISION			
12					
13	ARMAND SANCHEZ, et al.,	CASE NO. CV 11-7867			
14	Plaintiffs,	DECLARATION OF DR. THOMAS			
15	riamuns,	P. SCHMALZRIED			
16	vs.				
		Judge: Hon. Jacqueline H. Nguyen			
17	DEPUY ORTHOPAEDICS, INC., et				
18	al.,				
19	Defendants.				
20	CATHERINE SHELTON,	CASE NO. 2:11-cy-08082			
21	CHILEIGH D SHEET ON,	CHOE 110. 2.11 07 00002			
22	Plaintiff,	DECLARATION OF DR. THOMAS			
23	VS.	P. SCHMALZRIED			
24	a **	Judge: Hon. Dean D. Pregerson			
25	DEPUY ORTHOPAEDICS, INC., et				
	al.,				
26	Defendants.	,			
27					
28	Decl. of Dr. Thor	nas P. Schmalzried			
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I, THOMAS P. SCHMALZRIED, pursuant to 28 U.S.C. § 1746, hereby declare under penalty of perjury that the following statements are true and correct, to the best of my knowledge and belief:

- 1. I am a practicing orthopedic surgeon and the Medical Director of the Joint Replacement Institute in Los Angeles, California. I am also the principal for Thomas P. Schmalzried, M.D., A Professional Corporation, a California corporation,
- 2. I played no role in the manufacturing, packaging, labeling, regulatory submissions, sales, inspection, distribution, and adverse event and complaint reporting, handling or tracking for the Pinnacle Cup System. I had no control or influence over DePuy's manufacturing, packaging, labeling, regulatory, sales, inspection, distribution and adverse event and complaint reporting, handling or tracking decisions regarding the Pinnacle Cup System.
- 3. I was one of eight surgeons selected by DePuy who provided assistance to DePuy with the design of the Pinnacle Cup System. DePuy determined the final design specifications for the Pinnacle Cup System and the product labeling content.
- 4. The DePuy brochure, "Advancing High Stability and Low Wear" was created by DePuy. My only contribution to this brochure was a general educational summary (including references to thirty four scientific and medical articles as support for the data in this summary), written at the request of DePuy, entitled "High Stability, Low Wear Metal-on-Metal Bearings: Benefits, Risks, and Alternatives."

Decl. of Dr. Thomas P. Schmalzried

1	As the title reflects, this paper discusses the benefits, risks and alternatives to metal-					
2	on-metal bearings. The paper clearly outlines the special risks associated with all					
4	metal-metal bearings, and states my belief that "there is insufficient clinical data to					
5	demonstrate the overall superiority of any single bearing couple for all total hip					
6	patients" and "it is therefore reasonable to individualize the choice of bearing." The					
8	only Pinnacle-specific data in this educational paper was provided by DePuy and					
9	clearly labeled as "DePuy Internal Data."					
10 11	5. I was not a part of DePuy's internal complaint handling system for the					
12	Pinnacle Cup System and thus was not notified if DePuy received such complaints.					
13	6. I have never made any representations or statements to any physicians, or to					
14 15	any member of the public including plaintiff regarding whether a specific DePny					
16	orthopedic implant product was suitable for any specific patient. That is a decision					
- 11	made by the patient's physician and not by me.					
18	I declare under penalty of perjury that the foregoing is true and correct.					
20	Executed on $10/27$ 2011.					
21						
22	Jan che					
24	THOMAS P. SCHMALTRIED, M.D.					
5						
26						
7						
18	Decl. of Dr. Thomas P. Schmalzried					

EXHIBIT 2

## Case4:14-cv-04996-JSW Document1 Filed11/12/14 Page19 of 54

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	SUMMONS		650	FOR COURT U	SE ONL	Y CORTE		
NOTICE TO DEFEND	(CITACION JUDICIAL)			LD I AIIA 000	DE EM O	Oi(12)		
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	, Inc.; Johnson & Johnson Ser	vices, Inc.: Johnson &	&					
Johnson, Inc., DePuy	International, Ltd. (continued	d)						
YOU ARE BEING SUE	D BY PLAINTIFF: NDO EL DEMANDANTE):							
Tatyana Nakhimovsk								
NOTICE! You have been su	ed. The court may decide against you w	thout your hales havel you			- 77			
You have 30 CALENDAR served on the plaintiff, A left case. There may be a court Online Self-Help Center (we the court clerk for a fee walve may be taken without further There are other legal requestral service. If you cannot these nonprofit groups at the (www.courtinfo.ca.gov/selfnecosts on any settlement or at JAVISOI Lo han demandado continuación.  Tiena 30 DIAS DE CALEN corto y hacer que se entreguen formato legal cerrecto si de Puede encontrar estos formulatio de expodrá quitar su sueldo, dinere hay otros requisitos legales remisión a abogados. Si no programa de servicios legales (www.lawhelpcalifornia.org), ecolegio de abogados locales.	DAYS after this summons and legal pare or phone call will not protect you. Your form that you can use for your response.  w.courtinfo.ca.gov/selfhelp), your county form. If you do not file your response or warning from the court.  Illiements, You may want to call an attorn tafford an attorney, you may be eligible.  California Legal Services Web site (www.  iph), or by contacting your local court or or contration award of \$10,000 or more in a cast of the court of the co	rers are served on you to file written response must be in You can find these court for law library, or the courthouse the file with the second file with th	a written response proper legal form I ms and more informe nearest you. If you see by default, and you can atterney, incorprofit legal servalification of the court has a set be pald before it re sin escuchar surpara presentar unaprofegen. Su respulario que usted puritas de California (Managara presentación de perder el caso conoce a un abogadara obtener servicion el sitto web de Cou) o ponténdose estos exentos por inde arbitraje en un o	at this court if you want the nation at the purchased wages, if you may ware vices programmine Self-Heistatutory lien the court will a versión. Lea a respuesta por escueda usar par incumplicio, puede illados legales galifornia Legan contacto c	and his ecour California in the cour California in the california	ave a c 11 to her mila Cc ling fee, , and p il an at can lo ater ived fee is the ca macké into en mo que viola de y la cc vy la cc vy la cc sorte o vorte o	copy ar you ar you a, ask proper coate es an ase, on a esta a corte orte la pricio a	trty  and
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400 McAllister Street,	S.F., CA 94102							
Kenneth M. Seeger, Se	ophone number of plaintiff's attorney número de teléfono del abogado de eger Salvas LLP, 455 Market	l demandante, o del dema	endante que no t F., CA 94105	(415) 98	do, es 1-92	;): 60		
DATAUG 0 5 2014 (Fecha)	CLERK OF THE COURT	Clerk, by (Secretario)	D. STEI	PPE			eputy <i>djunt</i> e	
For proof of service of this s Para prueba de entrega de a	ummons, use Proof of Service of Su esta citatión use el formulario Proof	mmons (form POS-010).)	POS-04011					
[SEAL]	NOTICE TO THE PERSON SEI	RVED: You are served	03-070)).					
	1 as an individual defence 2 as the person sued und	lant. der the fictitious name of (	ispecify):			4		
	3. On behalf of (specify):	Sobryon e John	· C	To				
	under: CCP 416.10 (c	orporation)		6.60 (minor	.)			
	CCP 416,20 (d	efunct corporation)	CCP 41	6.70 (conse	rvate			
		ssociation or partnership)	[] CCP 41	6.90 (autho	rized	perso	n)	
	4. by personal delivery on	(date):						
orm Adopted for Mandatory Use		MMONS		Code at Obit	Dines 4		go 1 of	-
Judicial Council of California SUM-100 [Rev. July 1, 2009]	501	AUMIOTAD		Code of Civil I		re §§ 412 v.courlini		

## Case4:14-cv-04996-JSW Document1 Filed11/12/14 Page20 of 54

	SUM-200(A)
SHORT TITLE:	CASE NUMBER:
Nakhimovsky v. DePuy Orthopaedics, Inc. et al.	
INSTRUCTIONS FOR USE	
<ul> <li>This form may be used as an attachment to any summons if space does not p</li> <li>If this attachment is used, insert the following statement in the plaintiff or defer Attachment form is attached."</li> </ul>	permit the fisting of all parties on the summons. Indant box on the summons: "Additional Parties
List additional parties (Check only one box. Use a separate page for each type	of party.):
Plaintiff Defendant Cross-Complainant Cross	ss-Defendant
Thomas P. Schmalzried, M.D. Thmas P. Schmalzried, M.D. A Professional Corporation Does 1 through 20	

Page 2 of 2

Page 1 of 1

Form Adopted for Mandatory Use Judicial Council of Caffornia SUM-200(A) [Rev. January 1, 2007]

ADDITIONAL PARTIES ATTACHMENT
Attachment to Summons

## Case4:14-cv-04996-JSW Document1 Filed11/12/14 Page21 of 54

		ChyoRsen CM-01
ATTORNEY OR PARTY WITHOUT ATTORNEY (Native, State Box Kenneth M, Seeger (CSBN 135862)	number, and address);	PANTE CONTROLLED GW-01
Seeger Salvas LLP		SUR SURTY
455 Market Street, Suite 1530 San Francisco, CA 94105		UET
TELEPHONE NO.: (415) 981-92690	FAX NO.: (415) 981-9266	2011 AUD -5 ALONS
ATTORNEY FOR (Hamo): Plaintiff Tatyana Nak	himovsky	2014 AUC -5 All 10: 39
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Sa	n Francisco	Children ,
STREET ADDRESS: 400 McAllister Street		El Pier Feller
CITY AND ZIP CODE: San Francisco, CA 94	102	William Cilks
BRANCH NAME:	102	D. STEPPE
CASE NAME:		
Nakhimovsky v. DePuy Orthopaedic	s, Inc.	
CIVIL CASE COVER SHEET	Complex Case Designation	CASE NUMBER:
Unlimited Limited	Counter Joinder	CAC-91-516916
(Amount (Amount dernanded demanded demanded demanded demanded is	Filed with first appearance by defe	
exceeds \$25,000) \$25,000 or less)	(Cal. Rules of Court, rule 3.40)	2) DEPT:
Items 1–6 beld	w must be completed (see instruction	
1. Check one box below for the case type that		4,0
Auto Tort	Contract	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403)
Auto (22) Uninsured motorist (46)	Breach of contract/warranty (06) Rule 3.740 collections (09)	1
Other PI/PD/WD (Personal Injury/Property	Other collections (09)	Antitrust/Trade regulation (03)  Construction defect (10)
Damage/Wrongful Death) Tort	Insurance coverage (18)	Mass tort (40)
Asbestos (04)	Olher contract (37)	Securitles litigation (28)
Product liability (24)	Real Property	Environmental/Toxic tort (30)
Medical malpractice (45)	Eminent domain/inverse	Insurance coverage claims arising from the
Other Pt/PD/WD (23)	condemnation (14) Wrongful eviction (33)	above listed provisionally complex case types (41)
Non-PI/PD/WD (Other) Tort Business tort/unfair business practice (07)	Other real property (26)	Enforcement of Judgment
Civil rights (08)	Unlawful Detainer	Enforcement of Judgment (20)
Defamation (13)	Commercial (31)	Miscellaneous Civil Complaint
Fraud (16)	Residential (32)	RICO (27)
Intellectual property (19)	Drugs (38)	Other complaint (not specified above) (42)
Professional negligence (25)	Judicial Review	Miscellaneous Civil Petition
Other non-PI/PD/WD tort (35)	Asset forfeiture (05)	Partnership and corporate governance (21)
Employment Wrongful termination (36)	Petition re: arbitration award (11)	Other polition (not specified above) (43)
Other employment (15)	Writ of mandate (02) Other judicial review (39)	
		ules of Court. If the case is complex, mark the
ractors requiring exceptional Judicial manage	ment;	ules of Court. If the case is complex, mark the
a. Large number of separately represe	nted parties d. Large numbe	er of witnesses
b. Extensive motion practice raising dif	ficult or novel e. Coordination	with related actions pending in one or more courts
issues that will be time-consuming to	resolve In other coun	ties, states, or countries, or in a federal court
c. Substantial amount of documentary	evidence f, Substantlal p	osljudgment judicial supervision
3 Remedies sought (check all that apply): a. 💽	monetary b. nonmonetary;	declaratory or Injunctive relief c. v punitive
4. Number of causes of action (specify): Six		Instrument F
5. This case is is not a class a	action suit.	
<ol><li>If there are any known related cases, file and</li></ol>	serve a notice of related case. (You n	nay use form CM-015.)
Date: August 4, 2014		0
Adam R. Salvas	P -	
(TYPE OR PRINT NAME)	NOTICE	IGNATURE OF PARTY OR ATTORNEY FOR PARTY)
Plaintiff must file this cover sheet with the first	paper filed in the action or proceeding	g (except small claims cases or cases filed
under the Probate Code, Family Code, or We in sanctions.	lfare and Institutions Code), (Cal. Rule	es of Court, rule 3.220.) Fallure to file may result
<ul> <li>File this cover sheet in addition to any cover s</li> </ul>	heet required by local court rule.	1
<ul> <li>If this case is complex under rule 3,400 et sec</li> </ul>	, of the California Rules of Court, you	must serve a copy of this cover sheet on all
other parties to the action or proceeding.		
Unless this is a collections case under rule 3.7	40 or a complex case, this cover she	et will be used for statistical purposes only.
orm Adopted for Mandatory Use	IVIL CASE COVER SHEET	Cal. Rules of Court, rules 2,30, 3 220, 3,400-3,403, 3,740;

## Case4:14-cv-04996-JSW Document1 Filed11/12/14 Page22 of 54

CASE NUMBER: CGC-14-540916 TATYANA NAKHIMOVSKY VS. DEPUY ORTHOPAEDICS, II

## NOTICE TO PLAINTIFF

A Case Management Conference is set for:

DATE:

JAN-07-2015

TIME:

10:30AM

PLACE: Department 610

400 McAllister Street

San Francisco, CA 94102-3680

All parties must appear and comply with Local Rule 3.

CRC 3.725 requires the filing and service of a case management statement form CM-110 no later than 15 days before the case management conference. However, it would facilitate the issuance of a case management order without an appearance at the case management conference if the case management statement is filed, served and lodged in Department 610 twenty-five (25) days before the case management conference.

Plaintiff must serve a copy of this notice upon each party to this action with the summons and complaint. Proof of service subsequently filed with this court shall so state. This case is eligible for electronic filing and service per Local Rule 2.10. For more information. please visit the Court's website at www.sfsuperiorcourt.org under Online Services.

## ALTERNATIVE DISPUTE RESOLUTION POLICY REQUIREMENTS

IT IS THE POLICY OF THE SUPERIOR COURT THAT EVERY CIVIL CASE PARTICIPATE IN EITHER MEDIATION, JUDICIAL OR NON-JUDICIAL ARBITRATION, THE EARLY SETTLEMENT PROGRAM OR SOME SUITABLE FORM OF ALTERNATIVE DISPUTE RESOLUTION PRIOR TO A TRIAL.

(SEE LOCAL RULE 4)

Plaintiff must serve a copy of the Alternative Dispute Resolution Information Package on each defendant along with the complaint. All counsel must discuss ADR with clients and opposing counsel and provide clients with a copy of the Alternative Dispute Resolution Information Package prior to filing the Case Management Statement.

[DEFENDANTS: Attending the Case Management Conference does not take the place of filing a written response to the complaint. You must file a written response with the court within the time limit required by law. See Summons.]

Superior Court Alternative Dispute Resolution Coordinator 400 McAllister Street, Room 103 San Francisco, CA 94102 (415) 551-3876

See Local Rules 3.3, 6.0 C and 10 B re stipulation to judge pro tem.

Complaint

Ms. Nakhimovsky's Pinnacle Hip Systems failed in her body, causing excessive and toxic levels of cobalt and chromium, tissue and bone destruction, and pain and suffering that required Ms.

Nakhimovsky to undergo a complicated and risky surgery to remove and replace the defective implant.

#### PARTIES

- 2. Plaintiff Tatyana Nakhimovsky is a citizen of the State of California and resides in San Francisco, California.
- 3. On information and belief, Defendant DePuy Orthopaedics, Inc. ("DePuy") is a corporation organized and existing under the laws of Indiana with its primary place of business in Warsaw, Indiana. DePuy developed, manufactured, advertised, promoted, marketed, sold and/or distributed the Pinnacle Hip System that is the subject of this lawsuit.
- 4. On information and belief, Defendant Johnson & Johnson, Inc. ("J&J") is a corporation organized and existing under the laws of New Jersey with its primary place of business in New Brunswick, New Jersey. J&J developed, manufactured, advertised, promoted, marketed, sold and/or distributed the Pinnacle Hip System that is the subject of this lawsuit.
- 5. On information and belief, Defendant Johnson & Johnson Services, Inc. ("JJSI") is a corporation organized and existing under the laws of New Jersey with its primary place of business in New Brunswick, New Jersey. JJSI developed, manufactured, advertised, promoted, marketed, sold and/or distributed the Pinnacle Hip System that is the subject of this lawsuit.

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6.	On information and belief, Defendant DePuy International, Ltd. ("DIL") is
a corporation organ	nized under the laws of the United Kingdom with its primary place of business
in Leeds, England.	DIL developed, manufactured, advertised, promoted, marketed, sold and/or
distributed the Pint	acle Hip System that is the subject of this lawsuit.

- 7. On information and belief, Defendant Thomas Schmalzried

  ("Schmalzried") is a citizen and resident of the State of California and he resides in Los Angeles.

  His involvement in this case is described in detail in the following paragraph.
- 8. On information and belief, Defendant Thomas P. Schmalzried, M.D. A. Professional Corporation ("TPS Corp.") is a corporation organized and existing under the laws of California with its primary place of business in Los Angeles, California. Thomas P. Schmalzricd, M.D. is believed to be the sole shareholder and employee of TPS Corp. TPS Corp. and Schmalzried designed the Pinnacle Hip System hip implants that are the subject of this lawsuit. TPS Corp. and Schmalzried collect royalties for each hip implant sold, and in the last two years alone, they have collected more than \$3.4 million in such royalty payments. In addition to designing the Pinnacle Hip System hip implants that were implanted in Ms, Nakhimovsky and collecting royalties for the sale of Ms. Nakhimovsky's implants, TPS Corp. and Schmalzried were actively involved in promoting and marketing the Pinnacle Hip System hip implant. TPS Corp., by and through its shareholder, director, and officer, Dr. Thomas Schmalzried, was a "product champion" for the Pinnacle Hip System. In the orthopedics community, a "product champion" uses the reputation as a prominent orthopedic surgeon to encourage other orthopedic surgeons to use a particular orthopedic implant. In his role as a "product champion" for the Pinnacle Hip System, Dr. Schmalzried, on behalf of TPS Corp., induced the sale of Ms. Nakhimovsky's implant by making representations to orthopedic surgeons, including Ms. Nakhimovsky's orthopedic surgeon, that the Pinnacle Hip System was safe and effective. As a product champion for the Pinnacle Hip System, Schmalzried and TPS Corp. also played an

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integral role in DePuy's sale of the Pinnacle Hip System to Ms. Nakhimovsky. DePuy could not have sold the Pinnacle Hip System without the endorsement of Schmalzried, and Schmalzried's design and promotion of the implants were necessary factors in bringing the products to the market. Given their prominent and necessary role as a product designer and product champion, Schmalzried and TPS Corp. also had a substantial ability to influence DePuy's manufacturing and distribution process. For example, if Schmalzried believed that a change should be made to the design, manufacturing process, or warnings that accompanied the Pinnacle Hip System, DePuy would have been required to make these changes otherwise it would have lost Schmalzried's endorsement and would not have been able to sell the hip implant. Although TPS Corp. and Schmalzried had the ability to change the design and manufacturing specifications of the Pinnacle Hip System, they failed to do so after they learned that the product was defective. TPS Corp. and Schmalzried knew or should have known about defects in the Pinnacle Hip System at the time these products were sold to and implanted in Ms. Nakhimovsky. Despite this knowledge, Schmalzried and TPS Corp. did not disclose that information to Ms. Nakhimovsky or her doctors. Schmalzried and TPS Corp. had full knowledge of each report of failure of the Pinnacle Hip System. As reports of failures of the Pinnacle Hip System mounted, Schmalzried and TPS Corp. conspired with the other Defendants in this action to conceal this information from patients and orthopedic surgeons, including Ms. Nakhimovsky's orthopedic surgeons, and to deflect blame for the growing problems with the implants. Despite a legal duty to disclose information about the defects of which Schmalzried and TPS Corp. were aware to Ms. Nakhimovsky and her doctors, Schmalzried and TPS Corp. instead actively concealed these known defects and they instead deflected blame for the mounting failures by blaming the surgical technique of the implanting orthopedic surgeon. To this day, Schmalzried and TPS Corp. continue to conspire with the other Defendants in this action to conceal the true information about the defects in the Pinnacle Hip System, and Schmalzried and TPS Corp. continue their aggressive promotion of the defective Pinnacle Hip System.

9. The true names and capacities of Does 1 through 20 are unknown to
Plaintiffs. They are informed and believe and thereon allege that each of these Defendants are in
some way liable for the events referred to in this Complaint and caused damage to them.
Plaintiffs will amend this Complaint and insert the correct names and capacities of those
Defendants when they are discovered.

- through 20—was the representative, agent, employee, joint venturer, or alter ego of each of the other defendants and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the Pinnacle Hip System. Therefore, it would be inequitable for any Defendant to escape liability for an obligation incurred as much for that Defendant's benefit as for the other Defendants
- 11. DePuy, J&J, JJSI, DIL, Schmalzried, TPS Corp., and DOES 1 through 20 are collectively referred to herein as "Defendants."

#### FACTUAL BACKGROUND

## A. The Pinnacle Hip System Is Defective And Was Not Adequately Tested

12. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.



-5-

Complaint

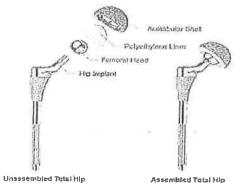
shell.

13. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, (3) a plastic (polyethylene)

[Iner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the

femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem.

The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular



14. While most hip replacements use a polyethylene *plastic* acetabular liner, DePuy's Pinnacle Hip System has a critical difference: it uses a *metal* acetabular liner. By using a metal acetabular liner and a metal femoral ball, the Pinnacle Hip System forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the Pinnacle Hip System, hundreds of patients—including Ms. Nakhimovsky—have been forced to undergo surgeries to replace the failed hip implants.

defect that forced DePuy to recall over 93,000 metal-on-metal ASR and ASR XL hip implants. While the exact nature of the common defect is still being investigated, Ms. Nakhimovsky believes that both hip implants suffer from one or more similar design or manufacturing defects that cause excessive amounts of cobalt and chromium to wear from the surface of the acetabular insert or from the femoral head. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness,

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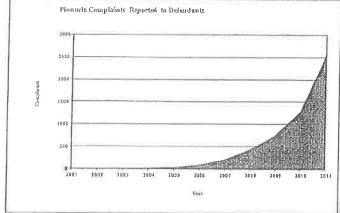
dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

- 16. The design of the Pinnacle Hip System was not sufficiently tested by the Defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose.
- Together with the other Defendants, Defendants Schmalzried and TPS 17. Corp. were integral participants in the design, manufacture, and sale of the Pinnacle Hip System to Ms. Nakhimovsky, and these Defendants' promotion of the Pinnacle Hip System was a necessary factor in bringing the product to the market and selling it to Ms. Nakhimovsky. For example, on numerous occasions, Schmalzried met with orthopedic surgeons, including Ms. Nakhimovsky's orthopedic surgeon, to promote the Pinnacle Hip Implant. At some or all of these meetings, a representative or representatives of DePuy was present. During these meeting, Schmalzried and the DePuy representatives assured the orthopedic surgeons, including Ms. Nakhimovsky's orthopedic surgeon, that the Pinnacle Hip System was safe, was the best product on the market, had an excellent track record and a low and acceptable failure rate. Schmalzried and the DePuy representatives continued to "defend" the Pinnacle Hip Implant even after they became aware of numerous and serious complications with the Pinnacle Hip System. Schmalzried and the DePuy representatives did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons, including Ms. Nakhimovsky's orthopedic surgeon.
- B. The Defendants Sold the Pinnacle Hip Implants To Ms. Nakhimovsky After They Knew They Were Defective, That The Implants Had Injured Others, And That The Implants Would Injure Her
- 18. It wasn't long after the Defendants launched the Pinnacle Hip System that reports of failures began flooding into each of the Defendants. For example, on May 4, 2002, the

Defendants received a complaint that a patient had to undergo a surgery to remove and replace the hip implant because the liner disassociated with the cup. DePuy closed its investigation of this complaint, finding that "corrective action is not indicated." Two weeks later, on May 17, 2002, the Defendants received another report that another patient had to undergo surgery to remove and replace a defective hip implant because the acetabular cup had loosened. Again, DePuy closed its investigation of this complaint, finding that "corrective

19. The Defendants would go on to receive hundreds of similar complaints reporting that the Pinnacle Hip System had failed due to premature loosening of the acetabular cup and that the failure had forced

action is not indicated."



patients to undergo painful and risky surgeries to remove and replace the failed hip component. As the chart to the right shows, reports to the Defendants that the Pinnacle Hip System had failed are skyrocketing. For example, by the end of 2008, Defendants had received more than 430 reports and by the end of 2009, that number had increased to almost 750. To date, the Defendants have received more than 2,500 reports claiming that the Pinnacle Hip System failed.

20. By the time the Defendants sold the Pinnacle Hip Systems to Ms.

Nakhimovsky, each of them, including DePuy, Schmalzried, and TPS, had received numerous complaints related to the Pinnacle Hip System. Consequently, each of the Defendants was fully aware that the Pinnacle Hip System was defective and that dozens of patients already had been injured by that defect. Based on this information, the Defendants should have recalled the Pinnacle Hip System before it was sold to Ms. Nakhimovsky. At minimum, the Defendants

should have stopped selling the defective implant when they became aware that it had catastrophically failed in several patients.

- 21. Despite their knowledge that the Pinnacle Hip System had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, the Defendants continued to sell the defective hip implant. In so doing, the Defendants actively concealed the known defect from doctors and patients—including Ms. Nakhimovsky and her doctor—and misrepresented that that the Pinnacle Hip System was a safe and effective medical device.
- 22. As numerous failures of the Pinnacle Hip Implant were reported to each of the Defendants, including DePuy, Schmalzried, and TPS Corp., they continued to actively promote, market and defend the defective products. For example, Schmalzried authored many marketing brochures for DePuy touting the safety and durability of metal-on-metal implants and specifically, the Pinnacle Hip System. These brochures containing Schmalzried's endorsements were given to doctors around the world, including Ms. Nakhimovsky's orthopedic surgeon, to encourage them to use the Pinnacle Hip System. In the brochure titled "Advancing High Stability and Low Wear," Schmalzried made several false representations about the quality and safety of the Pinnacle Hip System. For example, he said:
  - "Modular acetabular components, such as Pinnacle™, have the advantage of a high stability, low wear metal or crosslinked polyethylene bearing within the same construct."
  - "There is no mystery regarding the allure of metal-on-metal bearings: 1)
    larger diameter bearings have greater stability and 2) when properly
    positioned, the wear rate has been documented to be very low in vivo for
    three decades."

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•	"The wear of a well-made and well-mated metal-on-metal bearing is very
	low and decreases as the diameter increases."

- 23. Despite their knowledge that the Pinnacle Hip System was defective, Schmalzried and TPS also made several false representations about specific design elements of the Pinnacle Hip System that they claimed made it superior to other more safe hip implants on the market. For example, they said:
  - "Given that the material has high carbon content, metallurgy has little effect on bearing wear."
  - "Low-carbon materials exhibit higher wear than high carbon materials."
  - "There is little difference in the wear of high-carbon wrought or cast materials."
  - "Initial running-in wear decreases as the bearing diameter increases and/or the diametrical clearance decreases."
  - "Lower clearance has been associated with lower ion levels in vivo."
- 24. The Defendants' reason to conceal the defect in its Pinnacle Hip System is clear. In 2009 alone, DePuy brought in more than \$5.4 billion in sales and Schmalzried and TPS brought in more than \$2 million. Hip implant sales are critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of Johnson & Johnson's most profitable business groups. The Defendants were faced with a critical defect in one of their hip implant systems. The last thing the Defendants wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, each of the Defendants decided that they would continue to promote, market, and sell the Pinnacle Hip

System despite the fact that they each knew the product was defective. To this day, the Defendants continue to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

## C. Ms. Nakhimovsky's Pinnacle Hip System Was Defective And Failed, and Forced Her To Need An Additional Painful And Risky Surgery

- 25. On May 23, 2007, Ms. Nakhimovsky underwent a surgical procedure to implant the Pinnacle Hip System in her left hip. By this time, each of the Defendants had already received numerous reports that the Pinnacle Hip System had failed and they knew that the product was defective, but Defendants refused to disclose that information to Ms. Nakhimovsky, her physicians, or the public. Instead, the Defendants misrepresented to Ms. Nakhimovsky and her orthopedic surgeon that the Pinnacle Hip System was safe and effective. In reliance on these representations, Ms. Nakhimovsky's orthopedic surgeon made the decision to use the Pinnacle Hip System. If it were not for the misrepresentations made by each of the Defendants, including DePuy, Schmalzried, and TPS, Ms. Nakhimovsky's orthopedic surgeon would not have used the Pinnacle Hip System in Ms. Nakhimovsky's hip replacement surgeries.
- 26. As a result of the design, manufacture and composition of the Pinnacle Hip System, and its accompanying warnings and instructions (or lack thereof), Ms. Nakhimovsky's hip implants failed, causing his severe pain.
- 27. The failure of the Pinnacle Hip Systems also resulted in Ms. Nakhimovsky having toxic levels of cobalt and chromium in his body. The Pinnacle Hip System has an articulating surface that is made from cobalt and chromium. As the defective implant degrades in Ms. Nakhimovsky's hip, toxic amounts of cobalt and chromium made their way into her hip joint, into her Nakhimovsky stream, and circulated around her body. These toxic metals damaged the

tissue surrounding Ms. Nakhimovsky's hip joint and are likely to have accumulated in her heart, lungs, kidneys, liver, and brain.

28. An article published in the *Journal of Joint and Bone Surgery* describes some of the systemic effects that can be caused by exposure to high levels of cobalt and chromium in the Nakhimovsky, many of which were experienced by Ms. Nakhimovsky as a result of the defective Pinnacle Hip System implanted in his body. Dr. Stephen S. Tower, a noted orthopedic surgeon from Alaska, profiled two patients who had ASR hip implants. One patient (Dr. Tower himself) had a Nakhimovsky cobalt level of 122 μg/L and suffered from symptoms including impaired heart function, cognitive decline, depression, anxiety, headaches, irritability, fatigue, tinnitus, and high-frequency hearing loss. A second patient had Nakhimovsky cobalt levels of 23 μg/L and suffered from symptoms including cognitive decline, vertigo, hearing loss, groin pain, rashes, and dyspnea. Discussing these cases, Dr. Tower said:

Patients with metal-on-metal hips are at risk for cobaltism if the bearings wear excessively or if renal function declines. Most patients with metal-on-metal implants have higher serum cobalt levels than industrial workers and may be at risk for subclinical cognitive and cardiac impairment. A serum cobalt level of >20 µg/L is common in some groups of patients with metal-on-metal implants and may result in symptomatic neurological and cardiac cobaltism. Severe neurological and cardiac impairments have been reported in association with arthroprosthetic cobaltism when serum cobalt exceeds 60 µg/L.

29. On March 1, 2013, Ms. Ms. Nakhimovsky underwent a complex, risky, and painful surgery (known as a "revision surgery") to remove the Pinnacle Hip System from her body. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

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1	30. Having to go through a revision surgery has subjected Ms. Nakhimovsky to				
2	much greater risks of future complications than she had before the revision surgery. For example,				
3	several studies have found that a revision surgery causes a much higher risk of dislocation				
4	compared with an original hip replacement surgery. In one study conducted by Jan Phillips and				
5	her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who				
6	underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients				
7	who underwent a original hip replacement surgery. In other words, hip replacement patients who				
have undergone a revision surgery are almost <i>four times more likely</i> to suffer from a					
9	dislocation than those who have not. (Phillips CB, et al. Incidence rates of dislocation,				
10	pulmonary embolism, and deep infection during the first six months after elective total hip				
11	replacement. American Journal of Bone and Joint Surgery 2003; 85:20–26.)				
12					
13	31. As a direct and proximate result of the failure of his defective Pinnacle Hip				
14	System and the Defendants' wrongful conduct, Ms. Nakhimovsky sustained and continues to				
1.5	suffer economic damages, severe and possibly permanent injuries, pain, suffering and emotional				

## FIRST CAUSE OF ACTION

distress. As a result, Ms. Nakhimovsky has sustained and will continue to sustain damages in an

amount to be proven at trial, but which will far exceed the jurisdictional minimum of this court.

(Strict Product Liability) Against All Defendants

- 32. Ms. Nakhimovsky incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:
- 33. Defendants designed, manufactured, promoted, distributed, marketed, and sold the Pinnacle Hip System.

	34.	Defendants Schmalzried and TPS Corp. were integral parts of the sale of			
the Pinnacle Hi	ip Syste	em to Ms. Nakhimovsky, and these Defendants' promotion of the Pinnacle			
Hip System was a necessary factor in bringing the product to the market and selling it to Ms.					
Nakhimovsky.					

- 35. At all times material hereto, the Pinnacle Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was expected to reach, and did reach, prescribing physicians and consumers, including Ms. Nakhimovsky and his physician, without substantial change in the condition in which it was sold.
- 36. At all times material hereto, the Pinnacle Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:
- (a) When placed in the stream of commerce, the Pinnacle Hip System contained manufacturing defects, subjecting Ms. Nakhimovsky and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;
- (b) When placed in the stream of commerce, the Pinnacle Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting Ms. Nakhimovsky and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

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1	(c)	The Pinnacle Hip	System	was insufficiently	v tested:	and
- 1	· •		Discour	WHO IIIGUIII OIVIII	y restore	,

- (d) The Pinnacle Hip System was not accompanied by adequate instructions and/or warnings to fully inform Ms. Nakhimovsky or his physicians of the full nature or extent of the risks associated with its use.
- 37. Defendants knew or should have known of the dangers associated with the use of the Pinnacle Hip System, as well as the defective nature of the Pinnacle Hip System.

  Despite this knowledge, Defendants continued to manufacture, sell, distribute, promote and supply the Pinnacle Hip System so as to maximize sales and profits at the expense of the public health and safety. Defendants' conduct was done in conscious disregard of the foreseeable harm caused by the Pinnacle Hip System and in conscious disregard for the rights and safety of consumers such as Ms. Nakhimovsky.
- 38. Ms. Nakhimovsky and his doctor used the Pinnacle Hip System as directed for its intended purpose.
- 39. At all times herein mentioned, the Pinnacle Hip System was defective, and Defendants knew that it was to be used by the user without inspection for defects therein. Moreover, at the time of the use of the subject products, neither Ms. Nakhimovsky nor her physician knew or had reason to know of the existence of the aforementioned defects. Neither Ms. Nakhimovsky nor her physicians could have discovered the defects in the Pinnacle Hip System through the exercise of reasonable care.
- 40. The Pinnacle Hip System had not been materially altered or modified prior to its implantation in Ms. Nakhimovsky.

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41. As a direct and proximate result of the failure of the defective Pinnacle Hip System, Ms. Nakhimovsky suffered the injuries and damages as described herein.

## SECOND CAUSE OF ACTION

(Negligence)
Against All Defendants

- 42. Ms. Nakhimovsky incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:
- 43. At all times herein mentioned Defendants had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Pinnacle Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.
- 44. Defendants maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Pinnacle Hip System.
- 45. Defendants maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Ms. Nakhimovsky and his physicians as to the risks of the Pinnacle Hip System.
- 46. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the Pinnacle Hip System when they knew or should have known of said risks.

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	47.	Defendants' conduct was done in conscious disregard of the foreseeable
harm caused b	y the P	innacle Hip System and in conscious disregard for the rights and safety of
consumers sue	ch as M	s. Nákhimovsky.

48. As a result of Defendants' wrongful conduct, Ms. Nakhimovsky suffered injuries and damages as alleged herein.

### THIRD CAUSE OF ACTION

(Fraud)

Against DePuy, Schmalzried, TPS Corp. and DOES 1 - 20

- 49. Ms. Nakhimovsky incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:
- 50. As set forth above, Defendants made numerous representations to Ms.

  Nakhimovsky, and her orthopedic surgeon, that the Pinnacle Hip System was safe, effective and that Pinnacle Hip System had specific design elements that made it superior to other safer implants on the market.
- 51. These representations were knowingly false when made by Defendants and were made with the intention to deceive and induce Ms. Nakhimovsky and her doctors to use the Pinnacle Hip System. Furthermore, Defendants knew about defects in the Pinnacle Hip System at the time the Pinnacle Hip System was sold to and implanted in Ms. Nakhimovsky but did not disclose that information to Ms. Nakhimovsky or her doctors.
- 52. Ms. Nakhimovsky, and her doctors, at the time these representations were made, were ignorant of the falsity of the representations and were justified in relying on Defendants' representations.

- 17 -

	53.	As a proximate result of Defendants' fraudulent conduct, Ms.
Nakhimovsky	has be	en, and continues to be damaged in a sum yet to be fully determined, but will
be proven at t	rial, wh	ich exceeds the jurisdictional minimum of this court.

54. Defendants' acts, representations or omissions, as set forth above, were done in conscious disregard of Ms. Nakhimovsky' rights and with oppression, fraud, malice, justifying an award of punitive damages.

### FOURTH CAUSE OF ACTION

(Negligent Misrepresentation)
Against DePuy, Schmalzried, TPS Corp. and DOES 1 – 20

- 55. Ms. Nakhimovsky incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:
- 56. As set forth above, Defendants made numerous representations to Ms. Nakhimovsky, and her orthopedic surgeon, that the Pinnacle Hip System was safe, effective and that Pinnacle Hip System had specific design elements that made it superior to other safer implants on the market. At the time these statements were made, Defendants had no reasonable grounds for believing them to be true and Defendants made the representations negligently and carelessly and with the intention of inducing Ms. Nakhimovsky and her orthopaedic surgeon to use the Pinnacle Hip System.
- 57. Ms. Nakhimovsky, and her doctors, at the time these representations were made were ignorant of the falsity of the representations and were justified in relying on these representations.

- 18 -

	58.	As a proximate result of Defendants' conduct, Ms. Nakhimovsky has been
and continues	to be d	amaged in a sum yet to be fully determined, but will be proven at trial,
which exceeds	s the jur	isdictional minimum of this court.

59. Defendants' acts, representations or omissions, as set forth above, were done in conscious disregard of Ms. Nakhimovsky' rights and with oppression, fraud, malice, justifying an award of punitive damages.

#### FIFTH CAUSE OF ACTION

(Breach of Implied Warranties) Against DePuy and DOES 1 - 10

- 60. Ms. Nakhimovsky incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:
- 61. Prior to the time that the Pinnacle Hip System was used by Ms.

  Nakhimovsky, Defendants impliedly warranted to Ms. Nakhimovsky and her physicians that the Pinnacle Hip System was of merchantable quality and safe and fit for the use for which it was intended.
- 62. Ms. Nakhimovsky and her physician were and are unskilled in the research, design and manufacture of the Pinnacle Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Defendants in using the Pinnacle Hip System.
- 63. The Pinnacle Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

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6	54.	Defendants, by selling, delivering and/or distributing the defective Pinnacle
Hip System to N	Ms. Na	khimovsky, breached the implied warranty of merchantability and fitness
and caused Ms.	Nakhi	movsky to suffer severe pain and emotional distress, incur medical
expenses and in	cur a l	oss of earning capacity.

65. As a result of the aforementioned breach of implied warranties by Defendants, Ms. Nakhimovsky suffered injuries and damages as alleged herein.

#### SIXTH CAUSE OF ACTION

(Breach of Express Warranty) Against DePuy and DOES 1 – 10

- 66. Ms. Nakhimovsky incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:
- 67. At all times herein mentioned, Defendants expressly warranted to Ms. Nakhimovsky and her physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned Pinnacle Hip System was safe, effective, fit and proper for its intended use.
- 68. In utilizing the aforementioned Pinnacle Hip System, Ms. Nakhimovsky and her physician relied on the skill, judgment, representations and foregoing express warranties of Defendants.
- 69. Said warranties and representations were false in that the aforementioned Pinnacle Hip System was not safe and was unfit for the uses for which it was intended.

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- 21 -

# SEEGER • SALVAS LLP

ATTORNEYS AT LAW

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Adam R. Salvas E-mail Address: asalvas@seegersalvas.com

October 10, 2014

### VIA CERTIFED MAIL, RETURN RECEIPT REQUESTED

President Johnson & Johnson Services, Inc. One Johnson & Johnson Plaza New Brunswick, New Jersey 08933

Re: Nakhimovsky v. DePuy Orthopaedics, Inc. et al.

To Whom It May Concern:

Please find the enclosed Complaint, Summons, Notice to Plaintiff, Civil Case Cover Sheet and ADR Program Information Package.

Very truly yours,

Adam R. Salvas

# SEEGER • SALVAS LLP

ATTORNEYS AT LAW

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OCT 1 5 2014 Sd/6620

Adam R. Salvas E-mail Address: asalvas@seegersalvas.com

October 10, 2014

# VIA CERTIFED MAIL, RETURN RECEIPT REQUESTED

Alex Gorsky
Chief Executive Officer
Johnson & Johnson, Inc.
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Re: Nakhimovsky v. DePuy Orthopaedics, Inc. et al.

To Whom It May Concern:

Please find the enclosed Complaint, Summons, Notice to Plaintiff, Civil Case Cover Sheet and ADR Program Information Package.

Very truly yours,

Adam R. Salvas

# Case4:14-cv-04996-JSW Document1 Filed11/12/14 Page46 of 54

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	SUM-200(A)
SHORT TITLE:	CASE NUMBER:
Nakhimovsky v. DePuy Orthopaedics, Inc. et al.	
INSTRUCTIONS FOR USE  This form may be used as an attachment to any summons if space does not permit to the statement is used, insert the following statement in the plaintiff or defendant to Attachment form is attached."	he listing of all parties on the summons. pox on the summons: "Additional Parties
List additional parties (Check only one box, Use a separate page for each type of part	(y.):
Plaintiff V Defendant Cross-Complainant Cross-Defe	ndant
Thomas P. Schmalzried, M.D. Thmas P. Schmalzried, M.D. A Professional Corporation Does 1 through 20	

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6	Telephone: (415) 981-9260 Facsimile: (415) 981-9266  Attorneys for Plaintiff Tatyana Nakhimovsky  Entered Matter II	10 -5 -11 10:39				
21						
22	1. This is a product liability case involving a defective hip implant system,					
23	Plaintiff Tatyana Nakhimovsky had a Pinnacl	1				
24		cause excessive amounts of cobalt and chromium				
25		ert and from the femoral head, which in turn causes				
26	the hip implant to fail and the surrounding tiss	sue and bone to die. As a result of these defects,				
27 28	<sup>1</sup> The Pinnacle Hip Systems that were implanted in Ms. on-metal insert, a metal-on-metal femoral head, and a f	Nakhimovsky were comprised of an acetabular cup, a metal- emoral stem.				
		=1 =				

SEEGER · SALVAS LLP

Complaint

# SEEGER • SALVAS LLP

ATTORNEYS AT LAW

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001 17 2014

Adam R. Salvas E-mail Address: asalvas@seegersalvas.com

October 10, 2014

### VIA CERTIFED MAIL, RETURN RECEIPT REQUESTED

President DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581

Re: Nakhimovsky v. DePuy Orthopaedics, Inc. et al.

To Whom It May Concern:

Please find the enclosed Complaint, Summons, Notice To Plaintiff, Civil Case Cover Sheet and ADR Program Information Package.

Very truly yours,

Adam R. Salvas

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on-metal insert, a metal-on-metal femoral head, and a femoral stem.

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Ms. Nakhimovsky's Pinnacle Hip Systems failed in her body, causing excessive and toxic levels of cobalt and chromium, tissue and bone destruction, and pain and suffering that required Ms.

Nakhimovsky to undergo a complicated and risky surgery to remove and replace the defective implant.

#### **PARTIES**

- 2. Plaintiff Tatyana Nakhimovsky is a citizen of the State of California and resides in San Francisco, California.
- 3. On information and belief, Defendant DePuy Orthopaedics, Inc. ("DePuy") is a corporation organized and existing under the laws of Indiana with its primary place of business in Warsaw, Indiana. DePuy developed, manufactured, advertised, promoted, marketed, sold and/or distributed the Pinnacle Hip System that is the subject of this lawsuit.
- 4. On information and belief, Defendant Johnson & Johnson, Inc. ("J&J") is a corporation organized and existing under the laws of New Jersey with its primary place of business in New Brunswick, New Jersey. J&J developed, manufactured, advertised, promoted, marketed, sold and/or distributed the Pinnacle Hip System that is the subject of this lawsuit.
- 5. On information and belief, Defendant Johnson & Johnson Services, Inc. ("JJSI") is a corporation organized and existing under the laws of New Jersey with its primary place of business in New Brunswick, New Jersey. JJSI developed, manufactured, advertised, promoted, marketed, sold and/or distributed the Pinnacle Hip System that is the subject of this lawsuit.

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1	6. On information and belief, Defendant DePuy International, Ltd. ("DIL") is		
2	a corporation organized under the laws of the United Kingdom with its primary place of business		
3	in Leeds, England. DIL developed, manufactured, advertised, promoted, marketed, sold and/or		
4	distributed the Pinnacle Hip System that is the subject of this lawsuit.		
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- 7. On information and belief, Defendant Thomas Schmalzried

  ("Schmalzried") is a citizen and resident of the State of California and he resides in Los Angeles.

  His involvement in this case is described in detail in the following paragraph.
- 8. On information and belief, Defendant Thomas P. Schmalzried, M.D. A Professional Corporation ("TPS Corp.") is a corporation organized and existing under the laws of California with its primary place of business in Los Angeles, California. Thomas P. Schmalzried, M.D. is believed to be the sole shareholder and employee of TPS Corp. TPS Corp. and Schmalzried designed the Pinnacle Hip System hip implants that are the subject of this lawsuit. TPS Corp. and Schmalzried collect royalties for each hip implant sold, and in the last two years alone, they have collected more than \$3.4 million in such royalty payments. In addition to designing the Pinnacle Hip System hip implants that were implanted in Ms. Nakhimovsky and collecting royalties for the sale of Ms. Nakhimovsky's implants, TPS Corp. and Schmalzried were actively involved in promoting and marketing the Pinnacle Hip System hip implant. TPS Corp., by and through its shareholder, director, and officer, Dr. Thomas Schmalzried, was a "product champion" for the Pinnacle Hip System. In the orthopedics community, a "product champion" uses the reputation as a prominent orthopedic surgeon to encourage other orthopedic surgeons to use a particular orthopedic implant. In his role as a "product champion" for the Pinnacle Hip System, Dr. Schmalzried, on behalf of TPS Corp., induced the sale of Ms. Nakhimovsky's implant by making representations to orthopedic surgeons, including Ms. Nakhimovsky's orthopedic surgeon, that the Pinnacle Hip System was safe and effective. As a product champion for the Pinnacle Hip System, Schmalzried and TPS Corp. also played an

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integral role in DePuy's sale of the Pinnacle Hip System to Ms. Nakhimovsky. DePuy could not have sold the Pinnacle Hip System without the endorsement of Schmalzried, and Schmalzried's design and promotion of the implants were necessary factors in bringing the products to the market. Given their prominent and necessary role as a product designer and product champion, Schmalzried and TPS Corp. also had a substantial ability to influence DePuy's manufacturing and distribution process. For example, if Schmalzried believed that a change should be made to the design, manufacturing process, or warnings that accompanied the Pinnacle Hip System, DePuy would have been required to make these changes otherwise it would have lost Schmalzried's endorsement and would not have been able to sell the hip implant. Although TPS Corp. and Schmalzried had the ability to change the design and manufacturing specifications of the Pinnacle Hip System, they failed to do so after they learned that the product was defective. TPS Corp. and Schmalzried knew or should have known about defects in the Pinnacle Hip System at the time these products were sold to and implanted in Ms. Nakhimovsky. Despite this knowledge, Schmalzried and TPS Corp. did not disclose that information to Ms. Nakhimovsky or her doctors. Schmalzried and TPS Corp. had full knowledge of each report of failure of the Pinnacle Hip System. As reports of failures of the Pinnacle Hip System mounted, Schmalzried and TPS Corp. conspired with the other Defendants in this action to conceal this information from patients and orthopedic surgeons, including Ms. Nakhimovsky's orthopedic surgeons, and to deflect blame for the growing problems with the implants. Despite a legal duty to disclose information about the defects of which Schmalzried and TPS Corp. were aware to Ms. Nakhimovsky and her doctors, Schmalzried and TPS Corp. instead actively concealed these known defects and they instead deflected blame for the mounting failures by blaming the surgical technique of the implanting orthopedic surgeon. To this day, Schmalzried and TPS Corp. continue to conspire with the other Defendants in this action to conceal the true information about the defects in the Pinnacle Hip System, and Schmalzried and TPS Corp. continue their aggressive promotion of the defective Pinnacle Hip System.

1	PROOF OF SERVICE		
2 3	I am over the age of eighteen years and not a party to the within-entitled action. My business address is 2029 Century Park East, Suite 300, Los Angeles, California 90067. On November 12, 2014, I served a copy of the within document(s):		
4	1.	NOTICE OF REMOVAL OF ACTION TO THE UNITED STATES DISTRICT COURT UNDER 28 U.S.C. SECTION	
5		1441(b) (DIVERSITY)	
6		BY UNITED STATES MAIL by placing the document(s) listed above in a sealed	
7 8	×	envelope with postage thereon fully prepaid, the United States mail at Los Angeles, California addressed as set forth below.	
9 10		BY ELECTRONIC MAIL I caused the document(s) to be sent to the respective e-mail address(es) of the party(ies) as stated above. I did not receive, within a reasonable time after the transmission, any electronic message or other indication that the	
		transmission was unsuccessful.	
11 12	in a sealed envelope, postage fully paid, addressed as follows:		
13	Kenneth M. Seeger, Esq. Adam R. Salvas, Esq.		
14	Brian J. Devine, Esq.		
15	455 Market Street, Suite 1530		
	Te	n Francisco, CA 94015 lephone: (415) 981-9260	
16	Facsimile: (415) 981-9266 Attorneys for Plaintiff, Tatyana Nakhimovsky		
17		m readily familiar with the firm's practice of collection and processing correspondence	
18	for mailing. Under that practice it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on		
19 20	motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.		
21		eclare that I am employed in the office of a member of the bar of this court at whose the service was made.	
22	Ex	ecuted on November 12, 2014, at Los Angeles, California.	
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24		Brigette Price	
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q		- 1 -	

Barnes & THORNBURG LL ATTORNEYS AT LAW LOS ANGELES